EXHIBIT A

chronology
≈ 1991

FLEXIBLE MONITORING

MGH-Protocol Systems, Inc. Joint Development Project

Dates:

MGH Bedside Technology Task Force - May-November 1989
Request for Proposals; Selection of Protocol November 1989-March 1990
MGH-Protocol Letters of Intent - March, 1990
Prototype Development - March 1990 - March 1991
MGH Clinical Trials - April 1991 - October 1991
FDA 510k Pre-Market Approval - October 1991
System Availability to Market - December 1991

Co-Directors:

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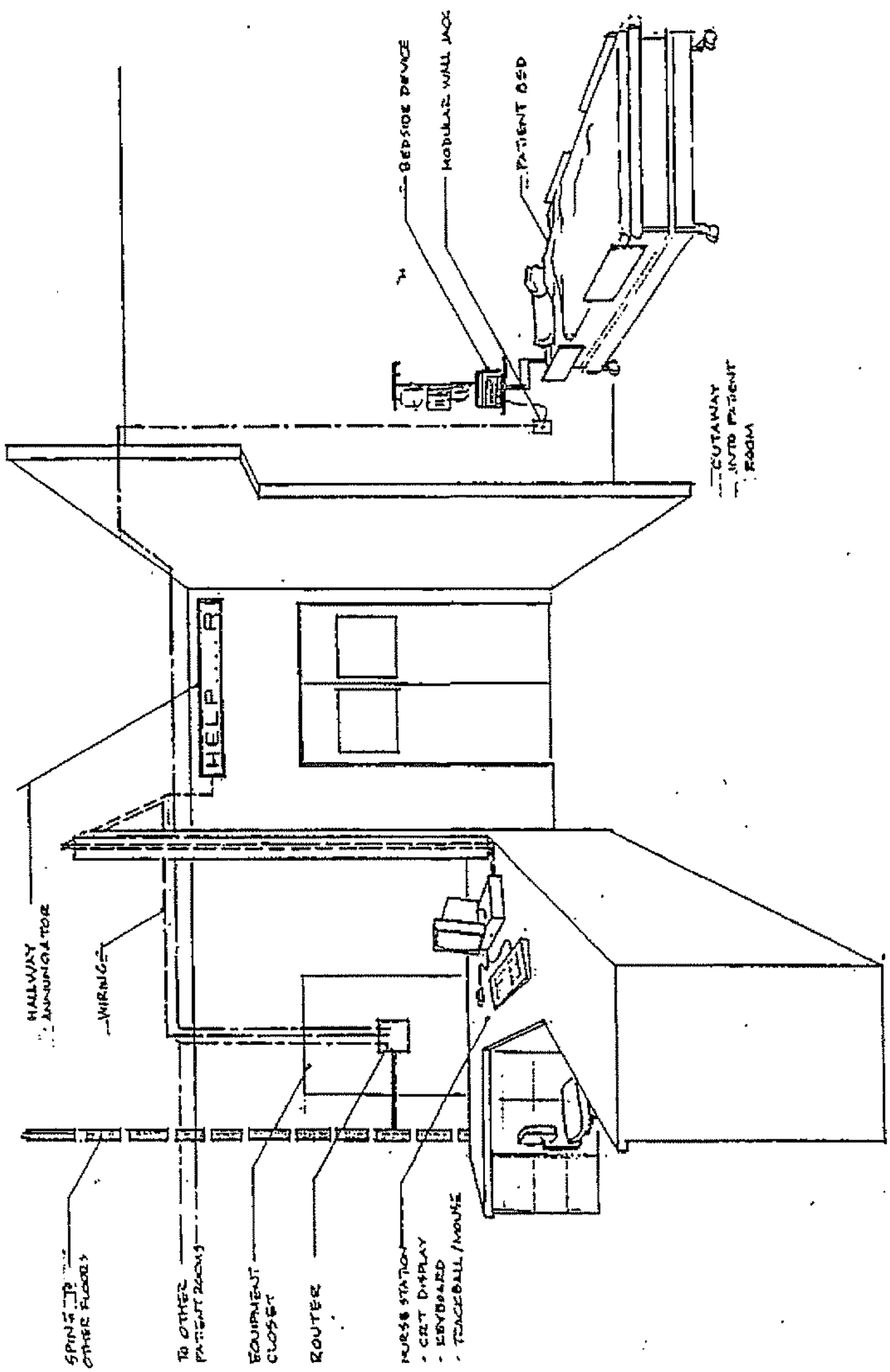
Mar 1989
drawn by Doug Bair
for Nat Sims



Mon 18th Feb

Thu 8:30 RSN

Arch mtg 8 9:30pm

I. MGH Task Force on Monitoring Strategy
  A. Membership
    1. Nucleating group
      a) Ron Newbower, Ph.D.
      b) Nat Sims, M.D.
      c) Tom Smith, Ph.D.
      d) Kate Walsh
      e) Jim Welch, C.C.E.
    2. Additional members?
      a) Biomedical Engineering
        1) Eileen Hall?
      b) Emergency Ward
      c) Information Resources
        1) John Limongelli?
      d) Medical Service
      e) Other Critical-Care Points of View
        1) Dick Teplick, M.D.?
      f) General-care nursing
      g) Research in monitoring technology
        1) Penny Ford?
      h) Other services?
  B. Objectives
    1. Educate each other
    2. Define objectives of monitoring in 1990's
    3. Formulate long-term strategy for monitoring
      a) Most flexible and cost-efficient allocation
    4. Additional?
  C. Agenda for sessions
    1. Presentation of patient transport problem and current approach
      a) Sims and Welch
    2. Presentation of in-room objectives of PDMS
      a) Informations resources
    3. Review planned move of SICU to twin towers
      a) Sims
    4. Review current increases in telemetry use
      a) ?
    5. Presentation of waveform database and its uses
      a) Penny Ford and Reid Rubsamen, MD

BEDS

MONITORS

INFUSION

NURSE LABOR

MATS MGH

COSTS

attached to minutes of 1/30/89 meeting

DRAFT

TASK FORCE ON BEDSIDE TECHNOLOGY STRATEGY

& further revised 4/10/89

Background:

Choices of the technologies which surround critically ill patients at the MGH are distributed across disciplines, units, and departments, and defy integration. Little consensus exists on long-term strategies in monitoring systems, infusion devices and automated data acquisition. No overall goal exists towards which we can work individually and collectively, as we populate the new towers.

A variety of individual successes have demonstrated the dramatic improvement in cost effectiveness when creative people forge a consensus on a specific solution to a specific problem and enlist industrial cooperation. These successful MGH efforts, include, in particular:

- procurement of new syringe-pump infusion technology by the pharmacy for antiobiotic administration
- development of even more novel infusion technologies to meet our needs for microinfusion of potent drugs in the SICU
- collaboration with a monitoring manufacturer to solve that problem of efficiently transporting critically ill patients through the hospital system, with continuous monitoring
- co-development of a new cath-lab hemodynamic recording system to meet the state-of-the-art needs of our new cath labs in an affordable manner
- surg O2 sys

Mission:

To facilitate more such individual successes, with their operational and financial benefits to the MGH, and to forge, in the process, an overall plan for the most cost effective use of these bedside technologies, we have formed this interdisciplinary task force to cut across departmental lines. It will meet and act as needed to:

*Maintain these needed "horizontal" lines of communication

*Review successful solutions in certain areas to draw lessons for other areas

*Appraise technological trends to serve as a focus for long range planning

*Review MGH problem areas and thus draw on the collective problem-solving creativity of the group and the departments the task force members represent

*Review the technology components of the planning process for the Twin Towers moves, to see where gaps may exist or opportunities may exist which require attention

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BEDSIDE TECHNOLOGY TASK FORCE MINUTES

Meeting of April 10, 1989

Present: L. Arguin (guest), R. Kacmarek, R.S. Newbower (presiding), N. Sims, T. Smith, J. Welch,.

1. Dr. Newbower began the meeting by describing some recent events. Dr. William Dec and Dr. Richard Teplick have accepted our invitation to joint the Task Force. Dr. O'Gara and Mr. Demonaco will be invited shortly. Our mission statement (updated draft attached) has been augmented by the Budget Committee's specfic request that we pull together the loose ends of equipment issues and funding needs for the Tower moves and its related "ripple" moves.

The most obvious of these is the 8-bed expansion of the SICU, for which no monitoring funds are currently budgeted. Moves of telemetry equipment and other ICU monitoring equipment on other floors will require expenses not yet identified.

Drs. Kacmarek and Sims both reported previous equipment planning efforts in connection with the architects and their consultants.

Action Item: R.S. Newbower will review the status of those efforts with Charlie Hall to avoid duplication of effort.

A consultant (Mitchell International) apparently inventoried existing equipment in ICU areas and elsewhere to identify purchase needs, but was not focusing on possible new strategies and was not dealing with "high-end" technologies.

2. The subject of the day was the PICU/NICU evaluation effort for new monitoring, the $420K "monitoring pool" for FY 89 has been allocated for this purpose. The goal is to stay within that budget while equipping 23 beds to replace the 19 previous beds. (16 NICU beds replace 12 previously, with 12 of those beds having intensive monitoring, versus 8 previously).

Ms. Arguin described the team evaluation process which narrowed 7 manufacturers down to 2 (Spacelabs and HP are the finalists, based primarily on their neonatal software and ease of use). Both finalists promise transport monitoring in the future, but have nothing comparable to Marquette's TRAM as yet.

Dr. Sims voiced strong concern about the compatibility issue, and the negative impact of incompatibility with the Marquette

monitoring in cardiac areas. Dr. Kacmarek responded by citing the importance of other factors and the need to avoid a de-facto standardization on a brand which was chosen some time ago, without an institutional mandate. Dr. Newbower reiterated the goal of the Task Force to build a viable consensus and to enforce it to the extent it offered savings or functional advantages, for the MGH. But we need to do so in a methodical way. The history of the units is relevant, and the existing diversity of needs and diversity of product offerings will take time to resolve.

Our long range goal is to define our monitoring needs in a way which is not constrained by currently available products, and then to meet that need by solicitation of proposals. Mr. Welch reviewed the interfacing between brands achieved in the Cath Lab as an interim measure, and advocated a functional spec rather than a brand-name spec. as a way of achieving compatibility.

Dr. Sims cited the need to get a commitment of an interim technology for transport monitoring in the PICU/NICU from either HP or Spacelabs, given their weaknesses and unproven potential capabilities in this area.

Action Item: Dr. Newbower will enter the negotiations with H.P. and Spacelabs.

There are both price and performance issues to be negotiated before a final "winner" is announced. This puts a strain on the pediatric unit while the decision seems to remain fluid, but is essential to achieving a good cost-effective result.

4-10-89/MGH

TASK FORCE ON BEDSIDE TECHNOLOGY STRATEGY

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A variety of individual successes have demonstrated the dramatic improvement in cost effectiveness when creative people forge a consensus on a specific solution to a specific problem and enlist industrial cooperation. These successful MGH efforts, include, in particular:

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Mission:

To facilitate more such individual successes, with their operational and financial benefits to the MGH, and to forge, in the process, an overall plan for the most cost effective use of these bedside technologies, this interdisciplinary task force has been created to cut across departmental lines. It will meet and act as needed to:

*Maintain the needed "horizontal" lines of communication between units and departments.

*Appraise technological trends and establish a long range plan for bedside technology at the MGH.

*Review MGH problem areas and thus draw on the collective problem-solving creativity of the group and the departments the task force members represent.

*Review the technology components of the planning process for the Twin Towers moves, to see where gaps exist or opportunities exist which require attention.

4-10-89/MGH

*Flag those areas where equipment compatibility would produce savings, and set in motion efforts to achieve them.

*Coordinate our various interactions with the biomedical device industry as we seek to fill our clinical needs in innovative and cost-effective ways.

Membership:

The departments, groups, or disciplines represented on this task force include Administration, Anesthesia, Clinical Engineering, Information Resources, Intensive Care Medicine, Intensive Care Nursing, Pharmacy, Respiratory Care and Technology Development.

Bedside Technology Task Force
Committee Members

William Dec, M.D.
Co-Director of Medical Intensive Care Units
Cardiac Unit
Bul - 1 x 8237

Harold J. Demonaco, M.S.
Director of Pharmacy
Pharmacy
Clinics Basement - 2501

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Edward Heller, M.D.
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James Welch, C.C.E.
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MONITORING TASK FORCE

Minutes of Meeting of May 30, 1989

Present: W. Dec, H. Demonaco, P. Ford, R. Kacmarek, R. Newbower (presiding), N. Sims, P. O'Gara, P. Smith, K. Walsh

Absent: E. Heller, J. Welch

Review of Minutes

The minutes of meeting of May 15, 1989 were reviewed, Dr. Sims pointed out that the design concept of the new SICU was the product of a design team involving all of the disciplines in the SICU, and the minutes should reflect that. The minutes as corrected were approved.

RICU/GRACU

Dr. Newbower updated the funding situation on the RICU/GRACU. It is in line for funding in the calendar year 1990, from the monitoring pool. The annual amount in that pool runs somewhat in excess of $400,000. Twenty beds of monitoring may exceed that allotment slightly, however the basic funding should be in place early in 1990, barring the unforeseen.

TOWER CAPITAL EQUIPMENT NEEDS FOR 1989

To help complete the discussion of capital equipment needs for Tower 1 which will occur prior to the next 1990 funding cycle, Dr. Newbower distributed a draft list reflecting prior discussions. The Task Force identified several items in the short-term and several items in the longer-term which had not been previously considered. On that basis, the draft list will be revised for review at the next meeting.

LONG-TERM MONITORING STRATEGY

The key paradox in developing a technologically more flexible approach to monitoring is that it may open up the Pandora's box of allowing monitoring in any bed. The flexibility of that may be desirable, but the opportunity may be abused. In order to assess that, the Task Force developed a short list of categories of patients whom we care for outside of ICU's who require or benefit from monitoring. Because of the other issues of caring for those patients, including the expertise of using the monitors wisely, it was considered essential that these patients always be clustered even though the clusters may grow or diminish from day to day. The monitoring technology could then follow those clusters, but would require strong medical control to prevent overuse or exhaustion of available resources.

The list of such clusters of patients which are currently foreseeable or currently exist is attached to these minutes. However, new procedures and new therapies will change that list over time, reinforcing the value of flexible escalation and de-escalation of monitoring intensity at any given bed. In short, the monitoring of patients now is limited by technological availability. Monitoring technology in the future will have to be managed by intelligent strategies. If it is not scarce, we still must manage and control usage.

The meeting adjourned at 5:00 p.m.

Patients Requiring Monitoring Outside ICU's

1). Patients requiring arrhythmia monitoring, but not intensive care: mostly ECGs, some pressures (invasive and non-invasive).

2) Those requiring invasive pressure monitoring but not intensive care: post PTCA's with sheaths in place or on low-dose nitro.

3) Pre-cardiac transplant patients in heart failure.

4) Patients on lytic theraphy; grafts, etc.

5) Patients with renal failure: peritoneal dialysis.

6) Chronically ventilated patients, with or without remote alarms.

7) Other clusters of intermediate care patients: pediatric, neuro, etc.

RSN/eah

MONITORING TASK FORCE

Meeting minutes of June 12, 1989

The minutes from the previous meeting were reviewed and accepted. The Chair opened discussions about technology requirements for the move and expansion of the SICU. Given the relatively high cost per bedside the Task Force felt that all possible alternatives for acquiring equipment based on demand should be explored. Mr. Welch was asked to explore acquisition alternatives with Marquette.

The meeting then turned to the main agenda item, a presentation of a rough draft of a general performance specification for monitoring systems at the MGH. Mr. Welch presented a concept based on a number of premises: 1) Eventually all in-patients in the MGH would require some form of monitoring. The information these future monitors provide must serve a number of purposes. Locating the patient would be the most basic form of monitoring. This information would be useful in coordinating "hotel" activities such as delivery of meals, housekeeping tasks, laboratory testing, etc. Beyond this base level are various intensities of physiologic monitoring. Physiologic monitoring is usually initiated in a low intensity state, such as ECG monitoring, and tends to escalate as the patient receives diagnostic and therapeutic care (eg cardiac catheterization, surgery). The intensity of monitoring should then de-escalates as the patient recovers. Non-invasive measurements can be substituted for more invasive measurements. 2) A comprehensive monitoring system should allow transitions between simple non-invasive monitoring and escalated levels of monitoring without the necessity to discontinue monitoring and replace the entire device. The system should be packaged so that essential monitoring functions can be transported with the patient. Such an architecture would reduce the time now required to make the transition from one monitoring system to another. 3) The most important feature of the monitoring system is the human interface. The monitor should be intuitive to operate requiring minimal user training. 4) In order to implement such a system, MGH must form partnerships with as few vendors as possible. 5) The monitoring system must be compatible with other information systems evolving at MGH. 6) The cost of implementing the system should be offset by measurable improvements in the overall quality and cost of health care delivery at MGH. 7) The system must be flexible to allow upgradability as requirements and technologies evolve.

Mr. Welch separated monitoring needs into three clusters, <u>patient location monitoring</u>, <u>ambulatory non-invasive physiologic monitoring</u>, and <u>fixed bed critical care invasive monitoring</u>. Patient location monitoring would provide the base level of monitoring and would be attached to all in-patients. The system would include a low cost patient connected transponder which would transmit patient location to a central display connected to a house wide network. This system is currently not available on the market. The hospital would need to develop the system in partnership with industry.

Ambulatory non-invasive physiologic monitoring would be based on the familiar telemetry scheme now used in the Hospital. Mr. Welch described developments in telemetry technology. New digital telemetry ystems will be capable of transmitting more physiologic data such as pulse oximetry and non-invasive blood pressure. At least one company is incorporating a mechanism to allow their telemetry system to handle invasive measurements as well. This feature would allow more intensive monitoring on floors where telemetry systems are installed. Dr. Sims commented that cables connecting the patient to the bedside monitor in the intensive care unit continues to be a problem in maintaining an organized patient environment. He supported using telemetry to eliminate the connection between the bedside monitor and the patient.

Fixed bed critical care monitoring would be based on concepts currently in place in the intensive care units. The integration of transport monitoring with the bedside monitor is a desirable feature. Mr. Welch noted that all the major manufacturers are developing a transport monitor as well as modules for pulse oximetry.

The task force challenged the premise that the capability for escalating monitoring technology should be available at all patient locations. Ms. Walsh raised the issue of whether the benefits of monitoring all patients justified the cost. Mr. Welch agreed that the benefit of the system must be measured against the overall cost to deliver quality patient care at MGH. Mr. DeMonaco noted that additional long-term costs could be incurred by not anticipating technological advances that would become accepted standards of care. He cited the cost of installation of bedside oxygen and suction outlets throughout the hospital. Dr. O'Gara introduced another dimension into the discussion of the practicality of escalating technology at any bedside, the need to concurrently provide the human expertise to care for patient requiring this escalated technology. He pointed out that patients requiring escalated monitoring also require more sophisticated care. Ms. Ford suggested a modification of the concept which would allow patients requiring escalated monitoring to be clustered on a floor and within a given service. Mr. Welch pointed out that portable monitors are now used throughout the hospital and their demand has continued to grow. One of the goals of the proposal was to replace these devices with a flexible system that provided additional benefits such as remote alarm annunciation. The task force decided that additional data would be useful in assess the effect of the proposed system on the quality and cost of care. Ms. Ford volunteered to investigate data sources within the hospital.

OVERVIEW
- Premises
  - all patients require some monitoring
    - existing manual method
      - mostly clerical
  - patients are frequently transferred
  - continuous monitoring is desireable
  - human factors are extremely important
    - shortage of medical personnel likely to continue
    - training is expensive
- Goals
  - minimum number of vendors
    - innovative partnership
  - compatibility of systems
    - HIS interface
    - other vendors
  - low relative cost
  - upgradeable

PATIENT LOCATION MONITORING
- target population
  - attached to all in patients
- system description
  - nurse station display (NSD) of patient location
  - NSD connected to house wide network
    - aides in scheduling "hotel" activites
      - housekeeping, dietary, lab tests, ect.
- characteristics
  - low cost
  - light weight
  - minimal human interface

PHYSIOLOGIC MONITORING
- Base level monitoring
  - ambulatory patients at significant risk
    - compromised cardiac condition
    - oxygen therapy
  - telemeters physiologic signals to central display
    - potential signals
      - ECG, pulse oximetry, NIBP
    - human factors considerations
      - ease of operation
        - intuitive controls
        - preconfiguration
          - formatable by operator
        - minimal steps for common tasks
    - real time display of signals
      - central station
        - waveform display
          - color format to separate information

(4)

        - documantation writer
        - alarms
          - high low level
            - semi-automatic setting
              - clamp on current values
              - visible indicator of setting
            - programmable latching / non-latching
              - audible
              - visual
            - visual indacator of armed alarms
          - retreivable alarm history
      - alarm annunciator
        - high specificity / selectivity
      - local display
        - displays all data
        - local control of configuration
          - eg ecg lead selection
          - alarm set / reset
          - portable
  - system can escalate to hardwire configuration
    - alternate power (AC)
    - additional signals
      - invasive BP
      - airway CO2
- Critical Care level monitoring
  - patients confined to bed
    - intensive care setting
    - invasive monitoring modalities
  - bedside monitor with transport capability
    - transport component
      - signals
        - ECG, 3 pressures
        - pulse ox
          - interchangeable probes
      - battery
      - display
      - mainframe interaction
        - download format
          - ecg lead, pressure labels, scales, ect.
      - durability
      - weight and size
        - mounting to bed
    - additional hardwired signals
      - potential signals
        - multichannel ECG
          - full diagnostic bandwidth
          - bedside electrocardiograph
            - 12 lead capability

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          transmission to central EKG facility
        specific lead fail identifier
        arrhythmia monitoring
          selectable alarm conditions
            selectable latching / non-latching
          waveform storage
        pacemaker identification
          external pacemaker
        front panel analog output
          gain selectable (IABP interface)
        defib synch output
      multichannel BP
        4 channels
          range -50 - +300 mmhg
            12 bit conversion
          ac or pulsed dc excitation
            excitation voltage less that 5V P-P
        selectable filtering
          .3 Hz (mean), 9, 12, 25
        automatic cath site labels
          identifies transducer site
        selectable pulse rate display
          annunciated beat display
      pulse oximetry
      non-invasive BP
      general purpose interface
        applications
          infusion pumps
          ventilators
        RS 232
        MIB
        analog
    human factors consideration
      ease of operation
        intuitive controls
      preconfiguration
        formatable by operator
          default settings
            lead display
            screen format
              separate vrs overlapped traces
            alarm limits
          automatic signal identification and label
          gain / calibration
      minimal steps for common tasks
        automatic PCWP detection
  display
    14inch diagonal
```

8 waveforms

(5)
(6)

7 lead ECG
color
waveform identification
digital display values
alarm setting
alarm condition
information priority
resolution
512 * 1024 non interlaced
formats
overlap
2 ECGs
lead labels
on screen cal 1 mV
background grid
resolution
1, 5, 25 mmHg
full screen calibrated pressure
high resolution grid
left / right scales
moveable curser
non overlap
individual pressure waveforms
calibrated grid
interfaces
HIS interface
MIB interface
intellegent alarm system
multichannel analysis
central station
signals displayed
interface to HIS
alarm management
annunciator system

11-10-89

DISCLOSURE

A FLEXIBLE BEDSIDE TECHNOLOGY SYSTEM

November 10,1989

James P. Welch
Nathaniel M. Sims

James P. Welch
Nathaniel M. Sims

BACKGROUND

Regarding bedside technology, hospital ~~s~~ patient care areas are at present typically divided into geographic regions comprising three general levels of acuity:

1-Intensive Care
2-Stepdown
3-General Floor

In Intensive Care, many bedside technologies are simultaneously in use. Many of the devices (particularly monitors) are installed permanently in the ICU cubicle, and are not movable. Some of these technologies are connected via proprietary networks. There is a high capital cost (approx $30,000/bed), and a high operating cost, associated with these areas of the hospital.

In Stepdown, monitoring systems (usually for continuous electrocardiography only) usually involve telemetry of physiological signals in defined areas (typically groups of 12 patient rooms taken together). The signals from the several patients are networked together via "central stations" where remote monitoring of the patient may be performed. These systems are not movable (they are confined to the geographic area in which the antenna is located), also have high capital cost (approximately $12,000/bed) and high operating costs, and generally lack the ability to monitor physiological systems other than ECG.

In General Floor areas of the hospital there tends to be little or no bedside technology other than portable infusion pumps. There is, however, an often-noted need for on-demand monitoring of individual patients at certain times such as the first few hours after a patient returns from the Post-anesthesia Care Unit, or from invasive procedures such as PTCA (angioplasty), etc. When physiological monitoring of a given patient is needed, the only options generally available are to install bedside monitors in every hospital bed (disadvantage: high

capital cost of about $15,000 for every bed in the hospital), or to bring some sort of "roving" monitor to the patient (disadvantage: physiological signals cannot easily be communicated from within the patient room to remote sites such as a nursing station).

We believe that the technolgies now in use in Intensive Care Areas and in Stepdown Units are not directly applicable to the growing need for additional surveillance of patients and devices in General Floor areas of hospitals. For example, the proprietary networks used in ICUs to connect bedside monitors serve to transfer data from the bedside to a central nurses station for viewing and interaction. However, they are expensive and limited, in that interface to devices (i.e. infusion pumps) other than those sold by the network manufacturer is impractical or impossible. An additional limitation is that current monitoring networks are not designed for use in general medical/surgical floors where only a few patients may require monitoring at any given time. Thus, implementing existing ICU-type monitor network systems in these areas is both impractical and expensive. The other option, that is medical band telemetry, is impractical when considering the cost to install multiple floors, the inherently high operating cost of telemetry equipment, and the limited number of patient parameters, or ~~pr devices~~ devices, which can be telemetered.

The management of other bedside technologies in the General Floor areas of the hospital presents additional problems. These other devices, such as infusion pumps and ventilators are applied as stand-alone instruments and typically rely on the proximity of an aware nurse to respond to critical data such as alarms. In the ICU, where the nurse:patient ratio is 1:1 or 1:2, management of these devices can be handled easily, but on the patient floor can become a determining factor in nurse staffing requirments.

We propose a flexible bedside technology system to provide the capability of moving monitors and portable devices to any patient bedside within the hospital and connect it to a network. The network allows the devices to communicate with a local clinical workstation and to ceiling-or wall-mounted alarm display units. Users at the workstation can communicate with and control the bedside devices remotely. The network can help hospital engineers manage information about the bedside devices themselves such as location, type of device and status of devices. The network has a low installation cost, and a low total capital cost for the hospital (about $2-3,000/hospital bed) because the network itself is inexpensive, and only a few [mobile] monitors [perhaps 4 per 30-bed patient floor] need to be purchased, in contrast to other options discussed above.

OVERVIEW:

The concept presented here integrates technologies available from the biomedical device industry, microcomputer industry, and the computer network industry. The concept allows technolgy to be brought to the patient rather than the current state which often requires moving the patient to the technolgy. Key componen ts of the concept include a

Flexible Bedside Technology Network (FBTN), an interface circuit integrated into bedside devices for connection to the FBTN, a hallway alarm annunciator which displays alarm messages to clinicians, and a Clinical Interactive Workstation.

FLEXIBLE BEDSIDE TECHNOLOGY NETWORK

The FBTN is based on the IEEE standard ethernet 802.3 communications standard. The network consists of Local Area Networks (LAN) on each patient care floor or area connected to each other through a "bridge" connected to a spine. A tap from the spine is connected to a bridge or router which is then connected to a number of repeater ports. Each port is wired to a specific bedside location and contains a specific ethernet address. The cable is unterminated at the bedside location. When not connected to a bedside device the network senses the non-termination and disconnects the port from the network. An ethernet address within the bedside technology identifies the type of device (example bedside monitor) and a specific identification code. Thus, a terminated bedside identifies the presence of a specific type of bedside technology in a specific location.

The router serves as a data filter keeping most of the network traffic limited to the floor or area. Selected traffic is allowed to pass through the router to the central spine for access by other devices. The central spine can be connected to other networks such as the Hospital Information Network to pass shared data such a patient identification. Data security and privacy is assu~~r~~red through the use of security codes implemented locally. The security codes allow~~s~~ select data to be accessed by predetermined individuals. For example, the respiratory therapy department may have an access code which would allow them to report the location of all ventilator patients but not the specific values reported at bedside, whereas the admitting physician may have access to all of this data for his specific patients.

BEDSIDE TECHNOLOGY INTERFACE

Each bedside technology device is equipped with an automatic-terminating ethernet transceiver. The transciever contains a code to identify the type of equipment and an identifier. Upon connecting to the network the transceiver senses whether the port is terminated. If it is already terminated by another device it transmit~~t~~s an identification code letting other devices on the network know it is active. If the port is not terminated, the tranceiver terminates the port and transmits an identification code.

HALLWAY ALARM ANNUNCIATOR

Each floor or area is equipped with a number of hallway alarm annuciators. The annunciator consists of a rectangular array of LEDs to permit the display of a brief message indicating the location and type

of alarm. At one edge of the array panel is a multicolor light bar. The illumination of a specific color indicates the severity of the alarm. The alarm annunciator is connected to the network either directly through a dedicated PC or through the Clinical Workstation.

CLINICAL INTERACTIVE WORKSTATION

The workstation is an <u>interactive display</u> which allows clinicians to view the status of devices on the floor or area and to interact with these devices as though they were at bedside. The workstation consists of a PC with a high resolution color display and a multitasking operating system. The workstation makes extensive use of icons and graphical displays to indicate device type, location, and status. The human interface to the workstation is primarily through a touch-screen or mouse. Disk storage within the workstation allows the archiving of patient data such as snapshots of waveforms and trend data. Input devices such as magnetic card readers and bar-code readers allow keyless data entry of data such as patient identification.

<u>The primary display consists of a architectural "floor plan" of the specific patient floor</u>. <u>Icons</u> within a patient room indicates the presence of a specific device. A monitor is indicated by a heart icon which flashes with each ECG "R" wave. A ventilator is indicated by a concertina bellows which empties with each mechanical breath. An infusion pump is indicated with an IV bottle which flashes to indicate delivery rate. Pointing to the icon of interest and "clicking" causes a window to "popup" displaying the virtual image of the front panel of the device. "Clicking" on a control on the virtual image causes the device to react in the same way as though the clinician were at bedside. All or some of these features could be locked out depending on the local medical practice. A device alarm would trigger the alarm annunciator and automatically display the virtual image on the workstation. Other displays provide graphical trend data, etc.

The workstation includes a stripchart recorder for documentation of waveforms. Waveforms can also be displayed on the workstation by calling the virtual image of the bedside monitor. Other output devices such as graphical printers provide documentation of screen dumps and formated reports.

The multitasking operating system allows the clinician to use the workstation for other applications while at the same time the workstation is performing network tasks. For example, the nursing staff may use the workstation to compile and report acuity levels.

APPLICATION

FOR

UNITED STATES LETTERS PATENT

A NETWORK FOR PORTABLE PATIENT MONITORING DEVICES

James P. Welch

Nathaniel M. Sims

"Express Mail" mailing label number LB160050517

Date of Deposit August 31, 1990

I hereby certify under 37 CFR 1.10 that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" with sufficient postage on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Mark McDermott

8-31-90

A NETWORK FOR PORTABLE PATIENT MONITORING DEVICES

Background of the Invention

This invention relates to interconnecting multiple patient care devices to a central location (such as a nurses' station) for observation and control.

A wide variety of patient care devices (PCDs) are currently available. Examples include vital signs monitors (which measure such parameters as ECG, non-invasive and invasive blood pressure, pulse oximetry, etc.), ventilators, and infusion pumps. PCDs typically are not permanently installed beside each bed in every hospital room in the general care areas of the hospital. One reason is, of course, the expense of such an arrangement, but another, equally practical reason is that patients who are cared for in these areas generally do not require routine use of PCDs.

Often, vital signs monitoring and use of infusion pumps are necessary temporarily, for example, for a few hours after the patient returns to the room from surgery. This is typically accomplished with portable PCDs brought to the patient's bedside. Thus, portable PCDs are used in general care areas on an ad hoc basis and it is common for a given PCD to be used in several rooms over the course of a few days. It therefore is difficult for a health care provider to determine the locations of the PCDs and of the patients who are using them, other than by physically looking in every room on the floor. Moreover, it is often helpful to a patient's recovery process to allow the patient to ambulate during the period that he or she is connected to the PCD; locating such a patient is usually done visually by searching the hallways.

General care patients that are using the PCDs are typically the most acute (i.e., medically unstable) patients on the floor (i.e., the patients that bear the closest monitoring by the floor's staff of health care providers).

8-2-91

NOTE: Manuscript as submitted August 2, 1991 to Society for Computer Applications in Medical Care (SCAMC) for presentation at meeting November 1991.

A Flexible System for Vital Signs Monitoring in Hospital General Care Wards Based on the Integration of UNIX-Based Workstations, Standard Networks and Portable Vital Signs Monitors

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Abstract

The article describes a study conducted on general surgical and thoracic surgical floors of a 1000-bed hospital to assess the impact of a new network for portable patient care devices. This network was developed to address the needs of hospital patients who need constant, multi-parameter, vital signs surveillance, but do not require intensive nursing care. Bedside wall jacks were linked to UNIX-based workstations using standard digital network hardware, creating a flexible system (for general care floors of the hospital) that allowed the number of monitored locations to increase and decrease as patient census and acuity levels varied. It also allowed the general care floors to provide immediate, centralized vital signs monitoring for patients who unexpectedly became unstable, and permitted portable monitors to travel with patients as they were transferred between hospital departments. A disk-based log within the workstation automatically collected performance data, including patient demographics, monitor alarms, and network status for analysis. The log has allowed the developers to evaluate the use and performance of the system.

Introduction

Rising in-hospital patient acuity, advances in therapeutic care, and limited ICU and step-down bed resources have created a demand for monitoring systems for electronic vital-signs surveillance of the status of patients located in general care nursing units. The limitations and cost of current proprietary monitoring systems designed for geographically limited ICU applications make current systems inappropriate for this new application.

Current ICU monitoring systems evolved from system design concepts originating in the early 60's before interoperable network technology was available. These early systems were developed in response to the specialized needs and sophistication of the ICU without regard for monitoring requirements in other areas of the hospital. The growing sophistication and complexity of these systems have escalated the per-bed cost to over $20,000. In addition, nursing care in the ICU, where the patient-to-nurse ratio is typically 1:1, contributes significantly to the overall cost of care.

As a result of the limitations of present monitoring systems, patients who require constant vital signs monitoring but do not require intensive nursing care are nevertheless admitted or transferred to intensive care settings, contributing to the congestion of valuable, high-cost ICU beds. Utilization studies have estimated that between 25% and 50% of patients admitted to the intensive care unit require surveillance monitoring, not intensive nursing care. [1-2] Substantial cost reductions, without sacrifice of safety, have been demonstrated by selectively transferring these patients to lower intensity, noninvasive monitoring units (NIMU). [3]

At the same time, at-risk patients on general care floors are attached to bedside standalone devices that are out of direct view of the central nursing station. Alarms are obscured by architectural barriers and may not be noticed by clinicians. The absence of a portable, multi-parameter, general care monitoring system causes an abrupt transition from full vital signs monitoring in critical care to minimal or no monitoring in general care.

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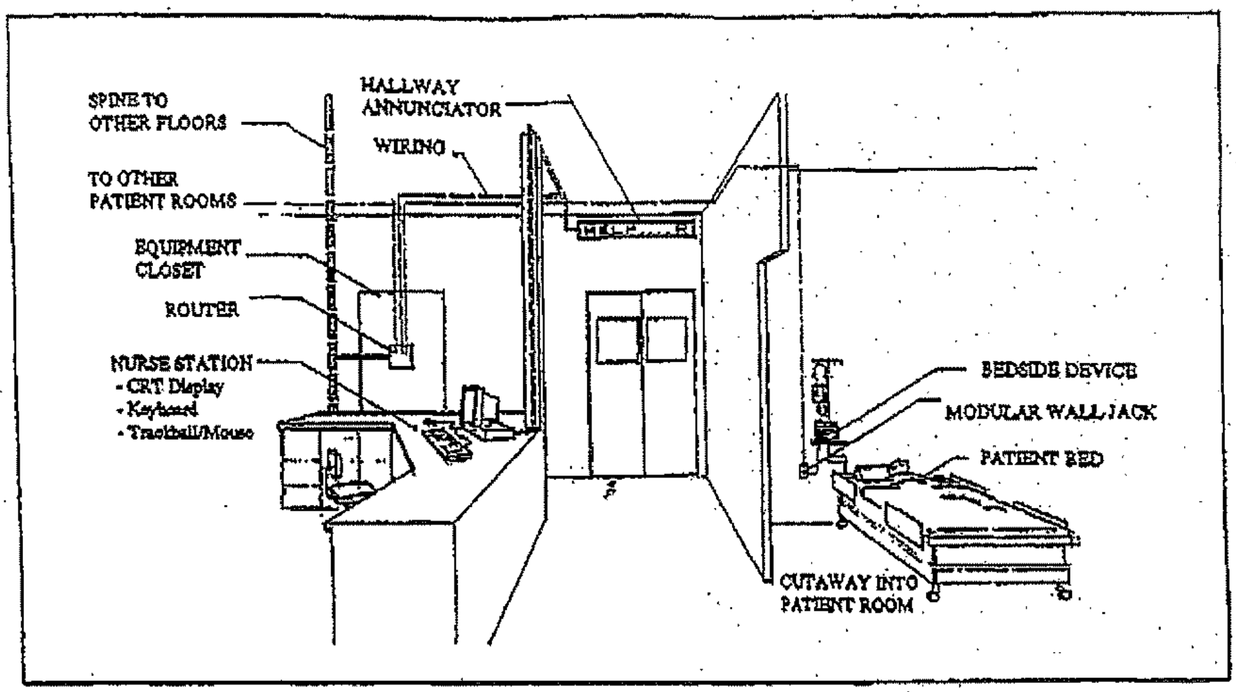

FIGURE 1 TARGET USER ENVIRONMENT

System Description

A cost-effective, network-based system for general care applications has been developed. It permits the moving of small, portable, multi-parameter vital signs monitors to any networked patient bedside for central surveillance and wide area alarm notification (see Figure 1). This same network-based system can be applied to any portable patient care device, such as infusion pumps and ventilators. The system allows monitoring of any patient location in the hospital without the cost of permanently installing monitors at every bed location. The portable monitors can travel with patients as they are transferred from one area of the hospital to another. This portability and the network's open architecture allow continuous vital signs monitoring, as well as an efficient, dynamic distribution of monitoring resources according to need. The portability of the monitor and the ease of connecting and disconnecting patients from the system allow monitor redistribution to be based on patient census, acuity levels, and monitoring needs.

The system uses standard network hardware and Unix-based workstation computers. Point-to-point cabling from each patient location back to a central data closet for each floor establishes a direct relationship between patient location and a specific network port. Floors are interconnected via network bridges to an IEEE 10Base5 backbone. A simple connection of the portable monitor to a wall jack allows the system software to recognize an active monitoring location. Patient demographics are entered at the workstation and downloaded to the monitor. Once stored in the monitor, this data travels with the patient, for increased efficiency when transferring patients to new locations. Data from the bedside monitor may be remotely accessed from any terminal connected to the backbone.

The system architecture is based on distributed processing, allowing load sharing as the system expands, as well as the addition of new software applications as they become available. System software and operating system are based on UNIX, X Windows, and the Sun Microsystems Open Look Graphical User Interface. In addition to the workstation, 20-character LED signs are positioned at strategic viewing locations on each floor. The signs display alarm messages to warn clinicians at positions remote to the workstation when patients are in critical alarm states.

The workstation's clinical user interface assumes the operator has little or no computer experience. Principle considerations in the human interface design included minimum training time, reinforcement of existing learned tasks, and minimum interaction with the workstation to retrieve primary information. Interaction is primarily through a point-and-click operation, using

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(3)

a standard trackball. Use of the workstation keyboard is limited to patient demographic entry on admission to the system.

Two graphical abstractions, a floor map and a series of virtual monitors, contain the primary user data: patient location and vital signs status (see Figure 2). The custom architectural floor map with icons positioned where patients are monitored provides an entirely graphical display of patient location and status. In the event of a patient alarm, the icon changes to a flashing red icon and the workstation "opens" the associated virtual monitor for viewing. The virtual monitor reproduces the data format and control features of the portable monitor at the patient's bedside. The clinician can interact with the virtual monitor as if at bedside to change function or call for additional data. Typical functions may include changing an ECG lead configuration, silencing a false alarm, or initiating a noninvasive blood pressure measurement. Duplication of the portable monitor in the virtual monitor abstraction establishes a consistent user interface to tasks associated with vital signs monitoring.

Certain actions affecting the function of the bedside monitor are not allowed from the workstation, because they may conflict with good clinical practice. Turning off all patient alarm settings at the workstation is not accessible. Also, illogical functions such as changing the label or zeroing an invasive blood pressure transducer are not accessible from the workstation. Other functions have security features to prevent inadvertent changing. An example is the default alarm settings which are accessible only to the clinical system administrator for that area.

The workstation screen can be placed into various viewing modes, depending on the priority placed on the continuous display of all patient waveforms. The Map mode places a large map on the display to accentuate patient location together with the display of a single, selectable virtual monitor. The Waveform mode places up to eight virtual monitors on the display with a small map so that more detailed vital signs of multiple patients can be displayed. A third mode under development permits display of multiple single waveforms together with a single expanded virtual monitor and a mid sized map. Consistency in the human interface is maintained across all of these modes.

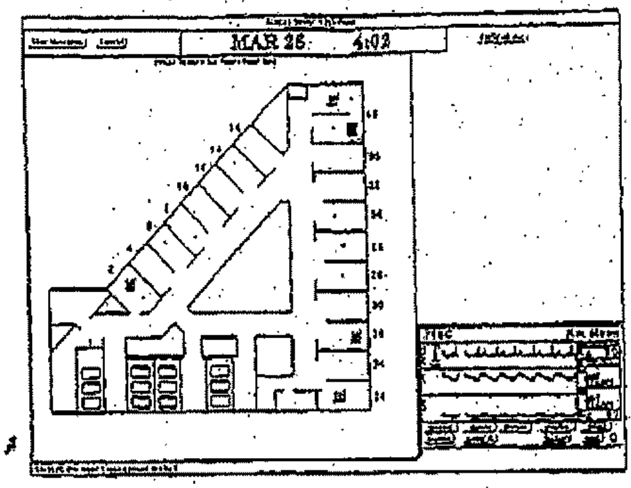

FIGURE 2 FLOOR MAP & VIRTUAL MONITOR

Additional features have been developed to enhance system function. An Alarm Manager has been created to improve the setting of multiple alarm thresholds for a given virtual monitor. It uses a double-headed slider graphical control which can be 'dragged' to the desired setting. An optional laser printer has been added to provide hard copy prints such as standard waveform strips, and vital signs trends.

Methods

A protocol was approved for human studies by the Subcommittee for Human Studies of the Massachusetts General Hospital. Verbal informed consent was obtained from patients connected to the system during the trial period. The system was implemented on two clinical general care floors, a general surgical floor and a thoracic surgical floor. Both areas had previously used non-networked "roving" instruments to monitor ECG and occasionally the oxygen saturation of their higher acuity patients. For this project, each floor was wired for all possible patient locations (36 for each floor). A total of twelve portable monitors (four on the general surgical floor and eight on the thoracic surgical floor) were provided. Vital signs monitoring included ECG, noninvasive blood pressure, and oxygen saturation (pulse oximetry).

The nursing staff was trained in the operation of both the portable monitor and the clinical workstation. Clinical criteria for "prescribing" vital signs monitoring were not altered for this study nor were acutely ill or unstable patients intentionally admitted or retained on the trial floor.

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(4)

The network architecture, communications protocol, workstation operating system, portable monitors and application software were evaluated for robustness, fault tolerance, and clinical acceptability. A disk-based log within the workstation automatically collected performance data for analysis. Data included patient demographics, monitor state changes (alarms), and network status. Each entry was time- and date-stamped within the log. The log has allowed the developers to evaluate the use and performance of the system.

Results

The trial period covered a 60-day period during which 159 patients were logged into the system in 46 out of the 72 possible locations. System use was greatest on the thoracic surgical floor, where 136 of the 159 patients were logged. Analysis of the monitoring location on both floors indicated an even distribution of monitored patients in proximity to the nursing station, with lower frequency at more remote locations. File analysis revealed 1807 connect/disconnect events distributed over the study group, indicating frequent ambulatory episodes.

The most frequently monitored vital signs, in decreasing order, were heart rate (ECG), oxygen saturation (SaO2), noninvasive blood pressure (NIBP), and temperature. The distributions of log data is shown in Figure 3.

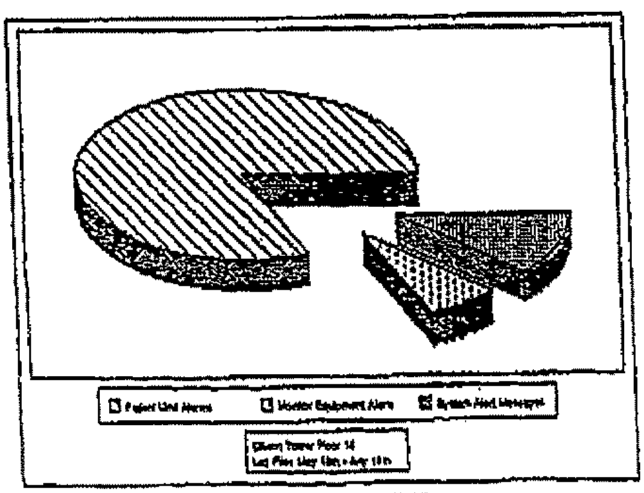

FIGURE 3 ALARMS & ALERT MESSAGES

The most frequently logged data was patient limit alarms (81%), followed by system alert messages (12%) and portable monitor equipment alerts (7%). Interviews with clinical staff, as well as analysis of sample bedside alarm printouts, indicated that the vast majority of the vital signs alarm violations were false positive alarms triggered by patient movement. System alert messages were log events captured by the workstation which indicated a user interaction. These included alarms suspension, loss of vital signs surveillance, unconfirmed patient demographics, and alarm off. Equipment alerts included vital signs sensor failures, low battery, and intentional disconnections of the portable monitor from the network to permit patient ambulation.

During the trial period there were 19 system failures, one due to hardware and 18 due to software. The hardware failure was a component failure in the workstation. This was corrected within 24 hours by the manufacturer. The software failures were the result of the automated file system filling available disk space. New software has been installed to correct this phenomena by downloading the file across the network to a central file server.

Discussion

Analysis of the data collected during the initial period of clinical implementation reported in this study permits a reasonably objective assessment of the overall system utility and performance. The lower utilization of the monitoring system on the general surgical care floor in comparison to the thoracic surgical floor reflects the lower acuity of the patient population during the trial period. The distribution of monitored locations on the two floors indicates that the clinical staff was able to continue to care for patients requiring surveillance "in situ" rather than transfer patients to beds closer to the nursing station, which had been the practice in the past. The system is similar to the noninvasive monitoring unit (NIMU) described by Krieger[3] except that the flexible network allows the number of monitored locations to expand or contract as needed. The combination of the workstation and the wide area alarm annunciators permitted the safe operation of the system without the requirement for full time monitoring technicians. The clinical staff found the workstation intuitive and easy to operate, but found some human factors limitations in performing certain tasks associated with the portable monitor (Ford-Carlton et al, in preparation).

The high incidence of false alarms demonstrated a weakness in the algorithm performance of the portable monitor for this

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application. Patients on general care floors frequently move and ambulate, resulting in motion artifact that corrupts the vital signs data. The proportional incidence of equipment alarms associated with poor sensor performance suggests that improvements in patient cables, electrodes and sensors may reduce false positive limit alarms since they contribute to limit violations. New algorithms and hardware are in development to reduce the incidence of false alarms. Similarly, software improvements have been made to the workstation to improve system reliability.

Cost analysis for the system may be viewed two ways; the cost per network location, or alternatively, the cost per monitored location. The difference in cost reporting methods is that the cost per networked location distributes the cost over all possible monitoring locations as compared to distributing the cost over the available monitors. The estimated cost per-network location is $3,000 and cost per-monitored location is $11,000. The cost per-monitored location represents about one half the cost-per-bed of a ICU monitoring system. An additional significant cost advantage is the expandability of the system. The monitoring capacity of the system can be expanded by merely adding more monitors until the capacity of the workstation is reached (current capacity is 14 monitors). Monitoring station capacity in turn can be expanded by adding additional servers. At full implementation (36 monitors and three workstations), per-network location and per-monitor location costs converge to approximately $9,000. This building block approach achieves a higher cost benefit than current ICU type systems because it leverages the network investment cost of the initial installation, and avoids hardware obsolescence as system needs expand.

Wagner et al analyzed the clinical course of a large group of intensive care patients.[3] Their study identified a significant number of patients who were admitted for continuous vital signs monitoring but who did not require the 1:1 ICU nursing care. The analysis showed that this low risk population did not receive a benefit commensurate with the cost of the ICU stay. The flexible monitoring system provides an effective, safe alternative to the ICU by decoupling the need for monitoring surveillance from the need for intensive nursing care. In addition, a patient care floor equipped with the network and workstation has the immediate capability to provide centralized vital signs surveillance for patients who unexpectedly develop complications and become unstable. In one case during the trail period, a patient's vital signs became unstable. The clinical staff was able to manage the patient until an ICU bed became available, and then efficiently transport the patient with the vital signs monitor.

Clinical acceptance of the system has been uniformly positive. Six more clinical areas, including a rehabilitation exercise lab, have been targeted for implementation over the next six months. The automatic data logging feature integrated into the workstation allows further study of the impact of this new concept in the general patient care population.

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MASSACHUSETTS GENERAL HOSPITAL

Boston, Massachusetts 02114

Martin S. Bander
Deputy to the General Director
(News and Public Affairs)
617-726-2206

October 7, 1991
For release October 7 after 3 pm

The Massachusetts General Hospital (MGH) announced today an experimental electronic vital-signs monitoring system aimed at improving patient care, increasing caregivers' efficiency, and reducing costs for both patients and hospitals.

The new system was designed for use with patients whose vital signs -- like heart rate, blood pressure, and blood oxygen level -- need constant surveillance but who do not necessarily need the one-to-one nursing of the intensive care unit (ICU), where hospitals' most sophisticated monitoring equipment has typically been found.

MGH staff in the Department of Anesthesia's Bioengineering Unit have been working on the concept of a flexible monitoring system for five years. Since 1990, the MGH has worked with Protocol Systems, Inc., Beaverton, Oregon, to develop the system, which uses computer networking technology to link small, portable monitors to central workstations. A six-month patient-care trial has just been completed on two patient floors of the MGH's new Ellison Building; other medical facilities across the country are also beginning trials. FDA approval for Protocol to market the system under the name "Acuity" is expected soon.

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"What this system represents, essentially, is a new way for a hospital to use its physical plant," said Ronald Newbower, PhD, the MGH's Vice President for Research and Technology Affairs. "For the past 30 years, electronic monitoring systems have only been available to a limited number of patients, because each monitor -- which costs between $15,000 and $25,000 -- is permanently mounted behind a bed."

By contrast, said Dr. Newbower, who is also an Associate Professor of Anesthesia (Bioengineering) at Harvard Medical School, the new flexible monitoring system costs far less -- between $2,500 and $4,000 per bed (see Attachment 2 for details). These monitors can be moved to the bedside of any patients who need one -- and simply plugged into a wall jack.

This capability, said Dr. Newbower, translates into increased continuity of care for the 80% of hospital patients who are in the "general care" category. Instead of being moved from location to location as their need for continuous vital signs surveillance changes, a greater number of these patients can remain on floors where there is nursing and medical expertise in their particular conditions; urology patients can stay on urology floors, chest surgery patients on respiratory care floors.

"This appears to be a patient care dream," said MGH General Director Dr. J. Robert Buchanen, "bringing high technology to the patient with less inconvenience, more continuity of care, and more efficiency -- and all at less cost."

Implementation of the system at the MGH has meant increased efficiency for nurses, who can keep more patients on regular floors

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and reduce the time spent looking for available beds in ICUs and other monitoring units. In addition, it has meant increased flexibility for the hospital because with the new monitoring system, a greater number of critically ill patients can be admitted to ICUs previously clogged by patients needing intensive monitoring but not intensive care.

The MGH and Protocol Systems also announced today a new study at the hospital to determine the time and cost savings that will result from use of the flexible monitoring system. Exact savings will be difficult to assess, and will vary from procedure to procedure and from floor to floor. To take one example, however, the hospital has estimated that with flexible monitoring available, a substantial number of the more than 800 patients admitted each year for angioplasty (a common cardiac procedure) could now be managed by cardiac specialists on general care floors rather than in ICUs or in intermediate care units. This change alone, affecting just one small group of patients, could save half a million dollars per year.

"Each flexible monitoring system consists of several small monitors linked to a Sun computer workstation and screen," said Nathaniel Sims, MD, an MGH cardiac anesthesiologist who, with James P. Welch, CCE, is one of the system's co-inventors. "The monitors are set up near the patient's bed on the regular floor. The computer is at the nurses' station at a central location on the floor; from there, caregivers can monitor the heart rate, blood pressure, blood oxygen level, and other variables of up to sixteen of the patients on the floor -- simultaneously."

Caregivers, he said, can also control the bedside monitors from the workstation using a "mouse" pointing device and "virtual images" of

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the waveforms and buttons of individual patients' monitors. If any measurement exceeds predefined limits, alarms sound and coded messages appear on electronic panels in the hallways.

"As we designed the workstation, we wanted to make sure it would be something nurses could use easily and intuitively," said Penny Ford-Carleton, RN, MS, MPA, who is co-directing (with Dr. Sims) the wider implementation of the flexible monitoring system. "We were concerned that moving computer-based technology into a general care area where nurses might not have had computer training could be overwhelming."

The original prototype, developed by Ms. Ford, Dr. Sims, Mr. Welch, and Protocol Systems engineers, was tested with MGH nursing staff, and nurses' feedback incorporated into design modifications. "Our overall aim, which we are working to achieve, is to create a system that increases -- not compromises -- efficiency," said Ms. Ford-Carleton.

"The MGH is considered a national leader in the forging of alliances with industry," said Dr. Newbower, who first envisioned a flexible monitoring system for general care floors a decade ago. "We are always working to develop ideas for products and technologies that will improve patient care -- both at our hospital and at other health-care institutions -- and then translating the ideas into cost-effective technology as quickly as possible."

In the case of the flexible monitoring system, Dr. Newbower and other MGH administrators put out a nationwide request for proposals within the medical electronics community. Because of their particular expertise, Protocol Systems was selected in February of 1990 to

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develop the system jointly with the hospital. The first systems were installed on two MGH patient floors (on a clinical trial basis) in April of 1991. Dr. Sims estimates that by November of this year, about two hundred of the hospital's beds (approximately one quarter of the currently non-monitored beds) will be available to the flexible monitoring system.

In its implementation of flexible monitoring, the MGH was able to save substantially by making use of computer cable which had been run during construction of the 23-story Ellison Building to every patient location. Future applications for the technology may include links to other hospital information networks, as well as the monitoring of other patient care devices, such as ventilators and infusion pumps.

Dr. Sims and Mr. Welch developed the concept for the Acuity system to improve patient care and to lower hospital costs simultaneously. The Massachusetts General Hospital (General Hospital Corporation) thus owns rights represented by the patent application and has licensed them exclusively to Protocol Systems.

The hospital would receive modest royalties if the Acuity system is successful, with specified portions distributed to the Department of Anesthesiology, Dr. Sims, and Mr. Welch. The royalties accruing to the hospital and the department would be directed back into research.

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Flexible monitoring system - Attachment 2
Comparative costs

The flexible monitoring system is currently installed on four general care floors and a cardio-pulmonary physical therapy unit at the Massachusetts General Hospital (MGH), with 143 beds wired for the system. However, because patients vary in the severity of their illness and their need for continuous surveillance of vital signs, only 15 to 25 percent of patients on these general care floors are actually being monitored at any given time.

By implementing the flexible monitoring system, the MGH has reduced the cost per bed of providing monitoring for these floors from the $15,000 to $25,000 required to purchase a traditional system (with a monitor at each bedside) to $2,500 to $4,000 per bed (depending on size of floor, number of monitors, and which model of monitor is chosen).

Before the end of 1991, the MGH is planning to expand its use of the system by an additional three general care floors. When this is done the total number of beds served by the flexible monitoring system will be 214. This represents approximately one-quarter of the currently non-monitored beds in the hospital. Decisions about further expansion of the system will be made at the end of this year.

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Flexible monitoring system - Attachment 1
Case history:
One patient's story – without flexible monitoring

Mr. R, a 74-year-old man with long-standing mild heart disease and colon cancer, was hospitalized at the Massachusetts General Hospital (MGH) last year for treatment of his tumor. On his second day he underwent an abdominal operation. After a brief stay in the recovery room, he was taken to Ellison 7, a general care floor specializing in the care of surgical patients. Two days later he was noted to have developed an irregular heart rhythm. This caused his blood pressure to drop, and he developed some difficulty breathing.

After numerous telephone calls, Mr. R's primary nurse located an available bed in an intensive care unit. After then finding a transport bed, the nurse, accompanied by a resident physician, moved Mr. R to the ICU so that he could be monitored and treated. The move took close to two hours. It also required the physicians and nurses on the ICU to familiarize themselves with the case history of their new patient.

Two days later, Mr. R was judged stable enough to return to Ellison 7. But because the nurses still wanted to keep a close eye on him, they put him in a room closer to the nurses' station, moving the patient who had been in that room further down the hall. The nurses also obtained an old cardiac monitor they could position in the hallway to display Mr. R's heartbeat. The monitor could not, however, be seen

from the nurses' station. It had no wide-area alarm to alert the nurses instantly in the event the patient developed more heart rhythm problems. It also could not measure blood pressure or blood oxygen levels.

With flexible monitoring:

Today, however, Ellison 7 is equipped with flexible monitors. At the first sign of cardiac trouble, Mr. R's nurse would pick up a monitor from the nurses' station, connect it to the patient, and plug the cord into a wall jack near his bed. The system would enable caregivers at the nurses' station to do continuous vital signs surveillance of the patient's heartbeat, blood pressure, and blood oxygen level. Medicines could be given intravenously, and once Mr. R's condition was resolved, he could remain on the monitoring system until nurses were sure the medications were working and his vital signs would remain stable.

The benefits of the flexible monitoring system; quicker diagnosis and treatment for the patient, greater continuity of care, more efficient use of time for hospital staff, and a more efficient use of patient beds. In addition, $994 per day are saved by managing Mr. R safely on a general care floor rather than in an ICU; other major operational costs -- more difficult to quantify -- are also reduced, including the costs of transporting patients from location to location around the hospital.

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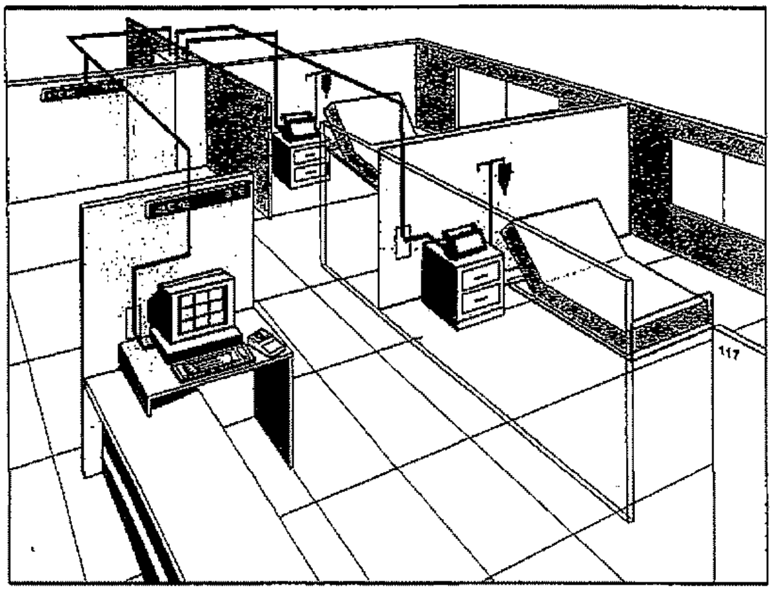
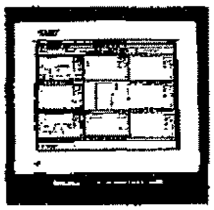
Welcome!

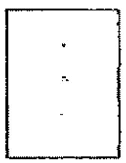


When we designed this system, we listened to people like you. We recognized that your work is more complicated than ever. You need to monitor your patients closely, and you strive to find time to provide the hands-on care that defines healing. Yet you haven't the time to learn elaborate procedures.

Propaq Monitor



Central Monitor



Bedside network jack

Message Panel

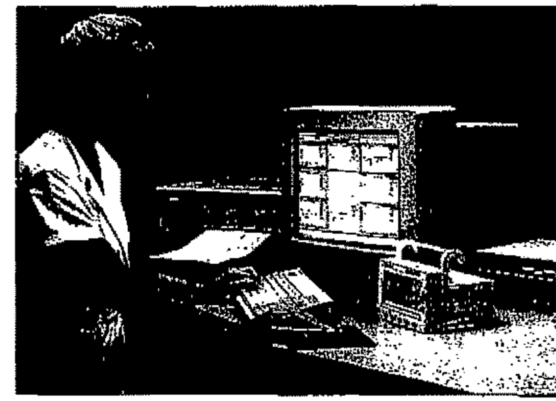
Using the Acuity System, which consists of four main components — portable vital sign monitors called Propaqs, a Central Monitor, bedside network jacks, and Hallway Message Panels (these are optional)— you can confidently monitor your patients' vital signs: anytime, anywhere. Acuity gives you the flexibility to bring monitors to patients rather than take patients to monitored beds.

The Propaq monitors display, either in-transit or at bedside, up to six of a patient's vital signs — heart rate/pulse rate, blood oxygenation levels, two invasive blood pressure channels, noninvasive blood pressure (Cuff) and temperature.

A Central Monitor saves you steps by displaying up to eight Propaqs at once, simultaneously monitoring up to sixteen Propaqs for alarm limit violations, and by showing you exactly where an alarm occurs. If your system includes a central station laser printer, you can print data snapshots or arrange for automatic printing-on-alarm right at the central station.

On the Central Monitor, colorful symbols show you patient status at a glance, and you can

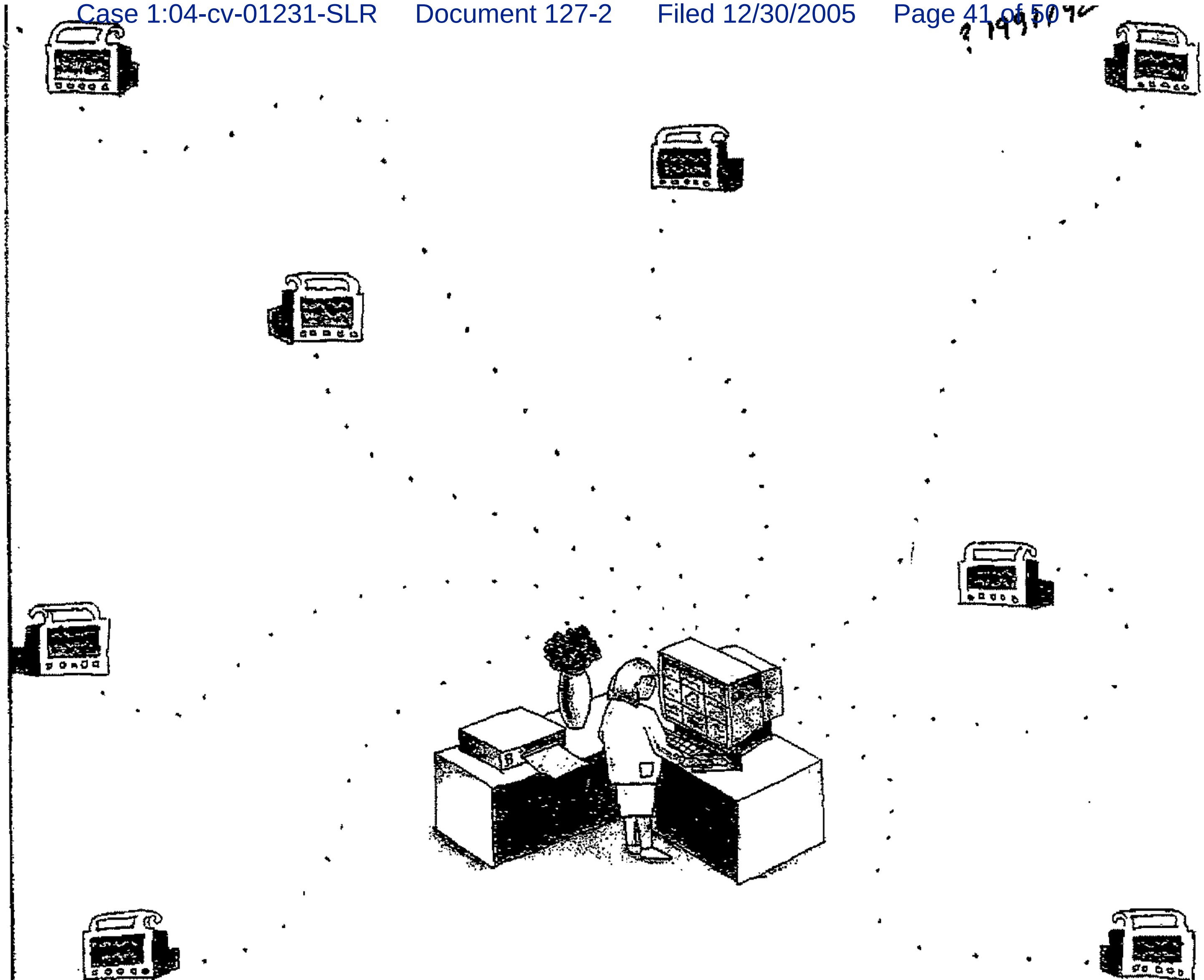
enter patient identification data, select alarm limits and respond to alarms. These features are important to you and your patients— because your time together will be better spent.



What we're giving you isn't just another piece of complicated equipment.

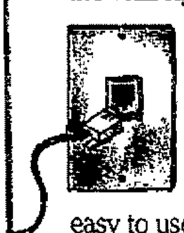
This system is friendly. And so is this manual. So relax, your patients are in good hands. Yours.

Now take a little time to become acquainted.



Now That You Can Monitor Our Monitors, There's No Limit To How They'll Be Used.

ER, L&D, PACU, special procedures, even medical/surgical floors, will find them invaluable. Because now the vital signs monitor that redefined portability can be



linked to a central station monitor in seconds. With a connection as simple as a phone jack.

You get two patient monitors in one. A bedside monitor. And a transport monitor.

Other advantages of our new Acuity™ system include a central station monitor so easy to use you won't know you're using a computer. It monitors up to 16 patients. One display mode even shows eight Propaq screens exactly as they look at the bedside.

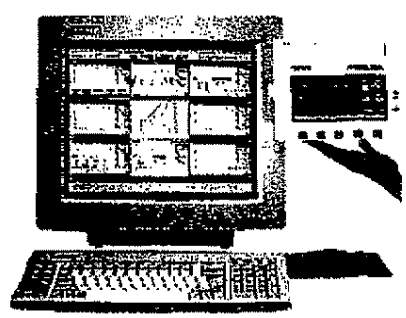
Tired of cutting and pasting printer strips? Our laser printer outputs in 8½" x 11" sheets.

Learn more by calling (800) 289-2500.

Monitoring our monitors is another step to better patient care.

Turn ordinary beds into monitored beds in seconds.

PROTOCOL® SYSTEMS, INC.



Each bedside PROPAQ can be configured with ECG, non-invasive and invasive blood pressure, NELLCOR® pulse oximetry, temperature, alarms, trending, and full annotation printer. Acuity is a trademark and both Protocol and PROPAQ are registered trademarks of Protocol Systems, Inc., 8500 S.W. Creekside Place, Beaverton, OR 97005-7107, (503) 526-8500. NELLCOR is a registered trademark of Nellcor Incorporated. All rights reserved.

≤ 1990
11 MGH press release

In 1988, Massachusetts General Hospital Defines New "Flexible" Patient Monitoring Concept

- Research Team Comprising Anesthesia, Nursing and Biomedical Engineering Practices Conduct Hospital Analysis

- PROTOCOL SYSTEMS Selected in Early 1990 as Co-developer for New Product.

1998
11 MGH Press Release
2

ACUITY
Patient Monitoring System

CONCEPT: **Highly Portable, Multiple-Parameter Patient Monitors Networked on a Central Station**

RESULT: **Make an Ordinary Bed a Monitored Bed in Minutes**

Bring monitoring to the patient rather than the patient to a monitored bed.

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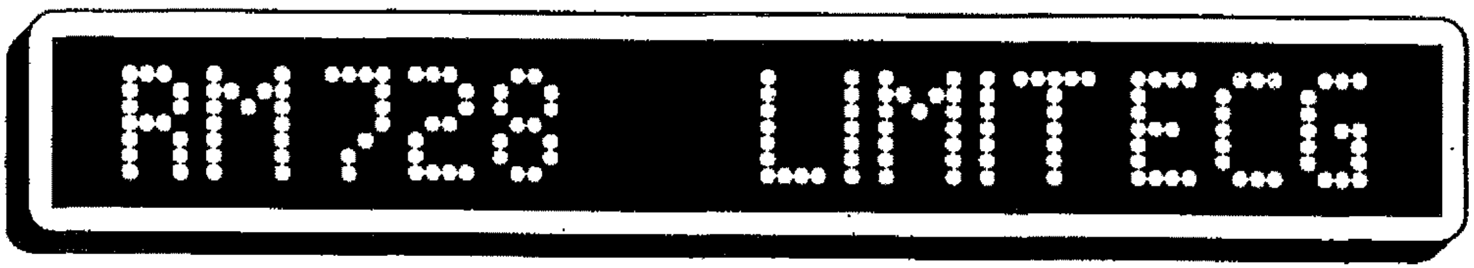
11 MGM press release

Message Panel



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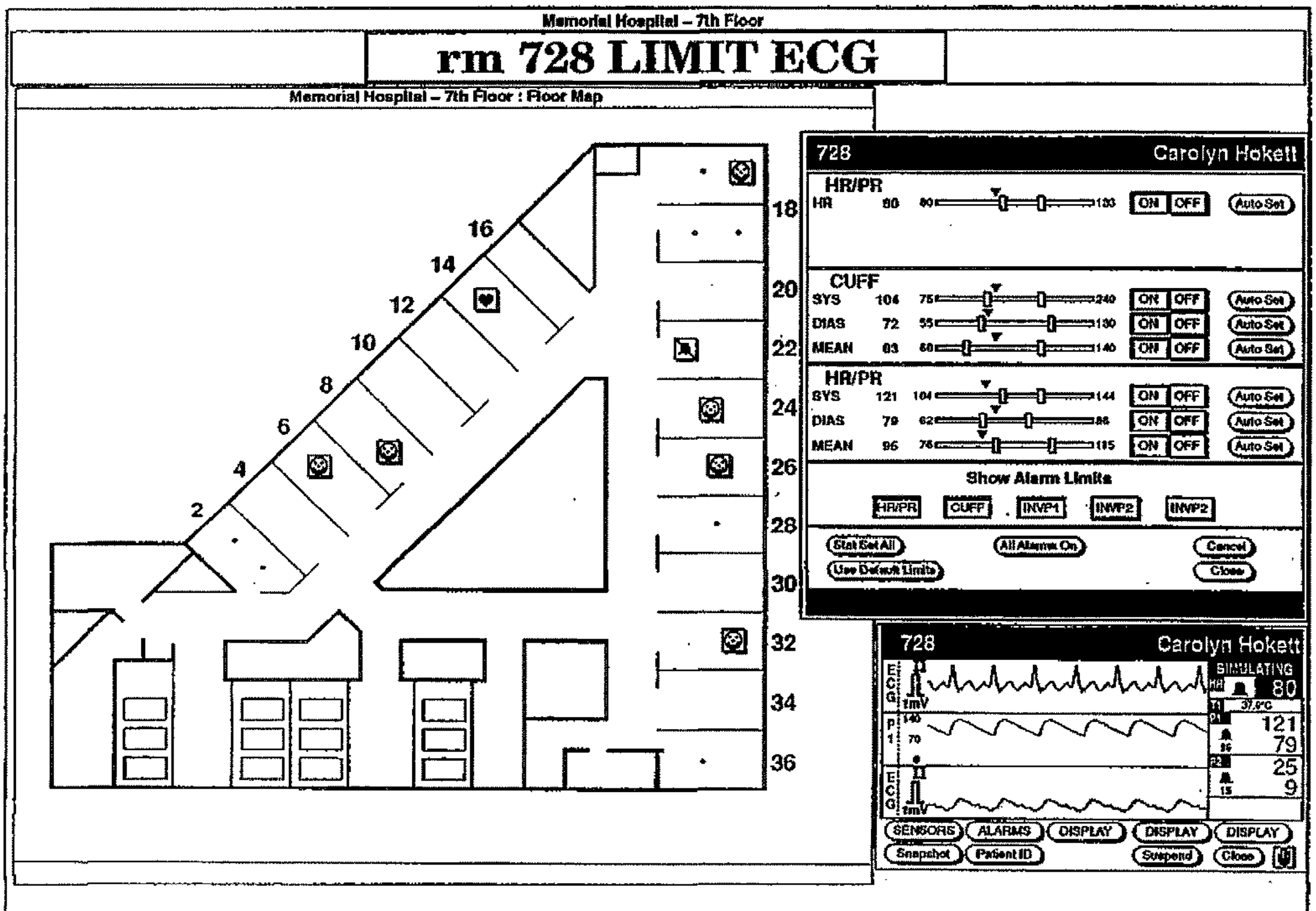
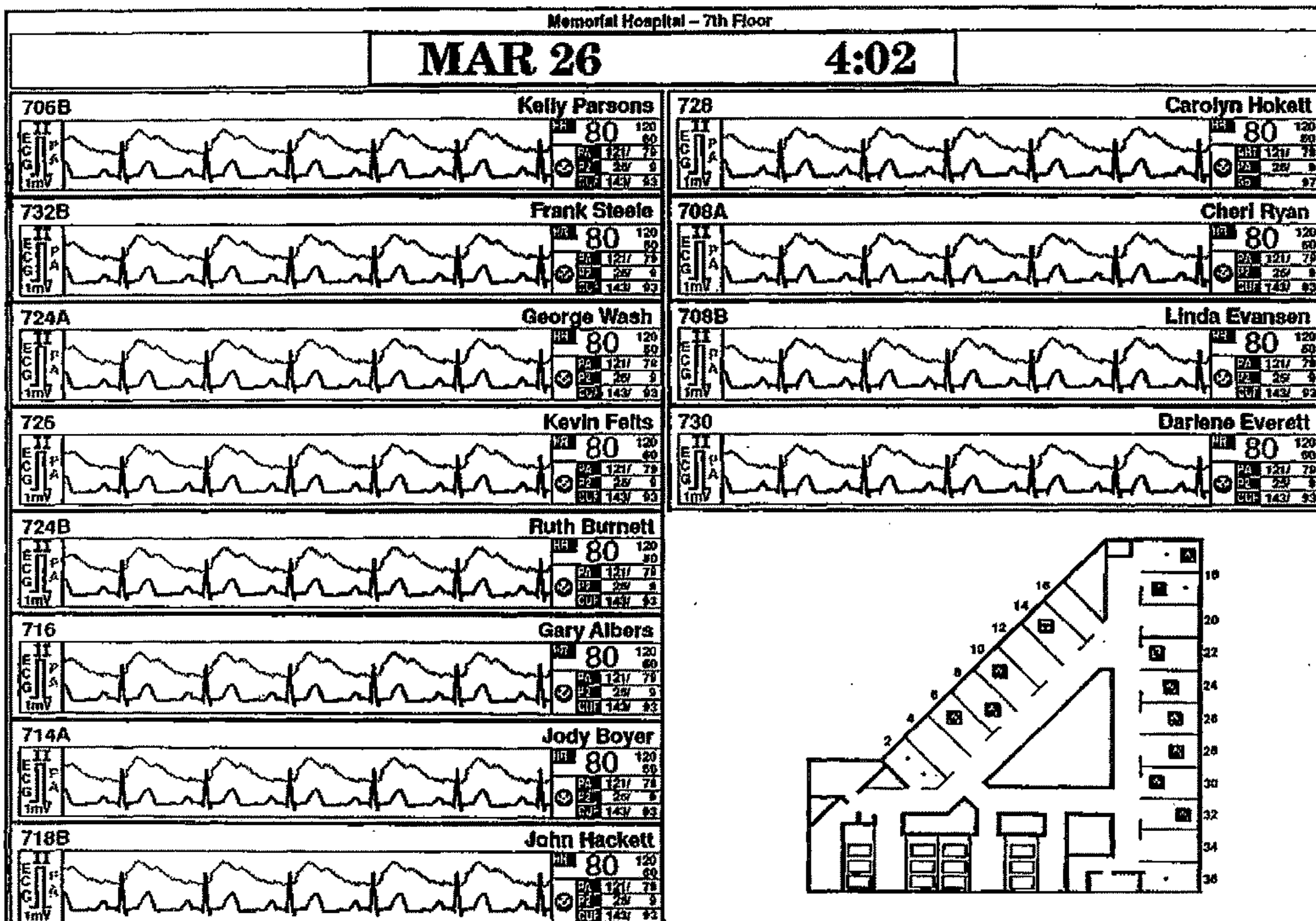
11 MGM press release 5

Map Mode Display



Waveform Mode Display

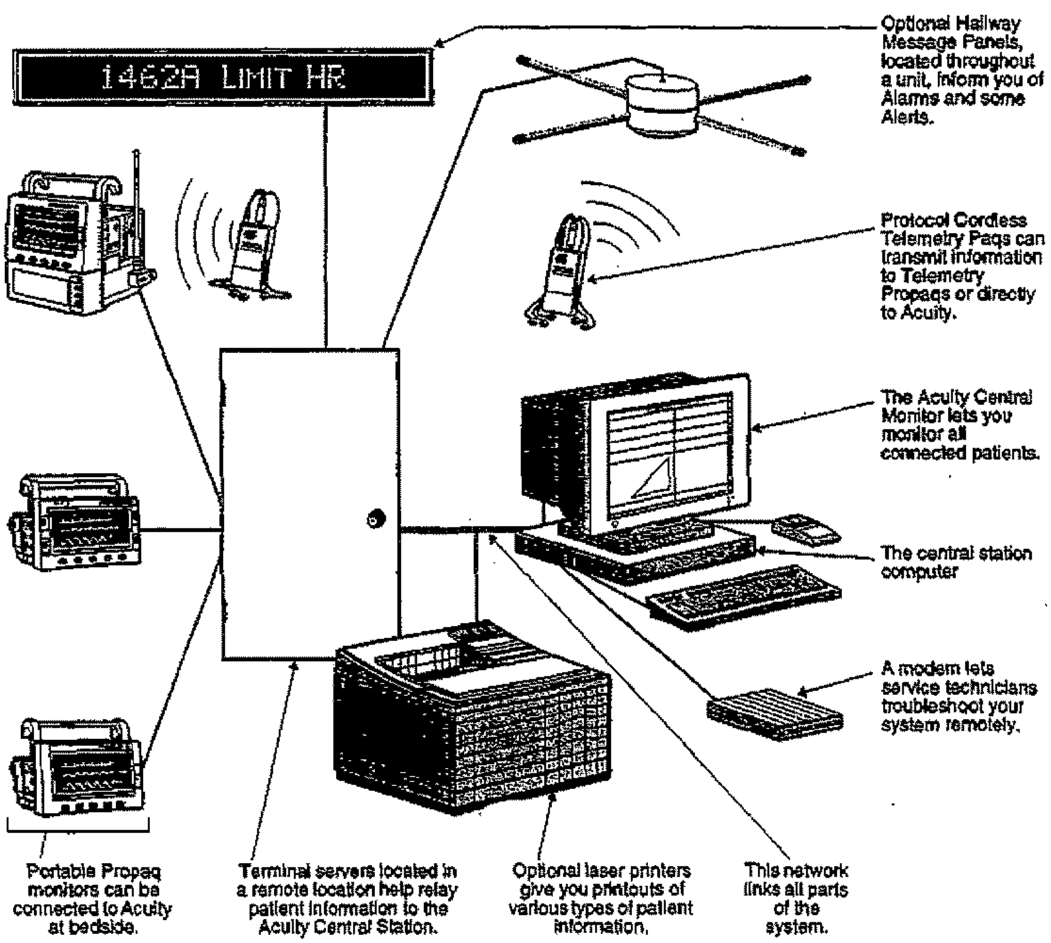


System Reference Guide

ACUITY® Flexible Monitoring®

PROTOCOL SYSTEMS INC.

Acuity Components



An Acuity System

Acuity Capabilities

The Acuity system you're using has been customized for your work site. Any Acuity Network Jacks placed near patient beds enable Bedside Propaqs to communicate with the Acuity Central Monitor.

Some key Acuity System capabilities are as follows:

- The Acuity Central Monitor simultaneously monitors *all* connected patients (the number depends on your Acuity System configuration).
- The Map on your Central Monitor Screen shows (a) all beds capable of accommodating an Acuity patient, (b) all Propaqs connected to Acuity, and (c) the status of the Propaq monitors and the patients. The Map Area can also include a separate Map Area showing status icons for Cordless Acuity Telemetry monitors/patients.
- At the Central Monitor, you can enter information, display patient information, remotely execute most Propaq functions, and respond to Alarms and Alerts.
- Optional laser printer(s) print patient Snapshots, Alarm Prints, and Review Prints.
- Optional Hallway Message Panels display messages that inform you of Alarms and some Alerts.
- Mobile patients can be monitored by Cordless Telemetry Paqs or by Propaqs using battery power. If a Propaq is then reconnected to Acuity, a limited set of numeric trends gathered during battery-powered monitoring transfer to Acuity.